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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/952, 741	11/25/97	HATADA	Y 2173-106P

<input type="checkbox"/>	HM11/0928	<input type="checkbox"/>	EXAMINER
BIRCH STEWART KOLASCH & BIRCH		SLOBODYANSKY, E	
PO BOX 747		<input type="checkbox"/>	ART UNIT
FALLS CHURCH VA 22040-0747		1652	
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		DATE MAILED:	09/28/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No. <b>08/952,741</b>	Applicant(s) <b>Hatada et al.</b>
	Examiner <b>Elizabeth Slobodyansky</b>	Group Art Unit <b>1652</b>

Responsive to communication(s) filed on preliminary amendments Nov 25, 1997 and Sep 11, 1998.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-19 is/are pending in the application.

Of the above, claim(s) 9, 11, and 17-19 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1-8, 10, and 12-16 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 2a

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **DETAILED ACTION**

The instant application is a 371 of PCT/JP96/01641.

The preliminary amendment filed concurrently with the application, amending claims 5 and 9, and adding claims 14-19 has been entered.

The preliminary amendment filed September 11, 1998 amending the specification to refer to the correct SEQ ID NOs, inserting the Substitute Sequence Listing, and amending claims 2, 3, 8 and 10 has been entered. A computer readable form of the Substitute Sequence listing filed September 11, 1998 has been entered.

Claims 1-19 are pending.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I , claims 1-8, 10 and 12-16, drawn to a DNA encoding alkaline liquefying  $\alpha$ -amylase, a vector containing said DNA, a cell transformed with said vector and a recombinant method of making of said enzyme.

Group II, claims 9,11 and 17-19, drawn to alkaline liquefying  $\alpha$ -amylase.

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The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Inventions I and II are patentably distinct because a DNA and a protein are different compounds each with its own chemical structure and function, and they have different utilities. The DNA molecules of invention I are not limited in use to the production of an enzyme of invention II and can be used as hybridization probes, and  $\alpha$ -amylase of invention II can be obtained by a materially different method such as by the biochemical purification.  $\alpha$ -amylase of the instant invention is known in the prior art and, therefore it does not make a contribution over the prior art.

During a telephone conversation with Dr. Mary Anne Liotta on September 17, 1998 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8, 10 and 12-16. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9, 11 and 17-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

*Priority*

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

*Drawings*

This application has been filed with formal drawings which have been approved by Draftsperson.

*Specification*

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

On page 10, line 16 and page 16, line 8, the specification refers to SEQ ID NO:1 where SEQ ID NO:2 is intended.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a DNA encoding alkaline liquefying  $\alpha$ -amylase. Applicants disclose one DNA molecule, the DNA encoding alkaline liquefying  $\alpha$ -amylase from *Bacillus* sp. KSM-AP1378 having SEQ ID NO:1. Several bacterial  $\alpha$ -amylases are known in the art. Claim 1 encompasses DNAs encoding said enzyme from all possible sources which would include fungi, plants, animals, etc. The specification does not disclose identifying characteristics which would allow to recognize a DNA encoding alkaline liquefying  $\alpha$ -amylase of all origins nor they are known in the art. Therefore, based on the instant disclosure, it is unpredictable whether any DNA encoding alkaline liquefying  $\alpha$ -amylase will have a similar structure. Thus, a DNA encoding alkaline liquefying  $\alpha$ -amylase lacks sufficient written description.

Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and /or the invention.

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Claims 12 and 13 are drawn to plasmid pAML100 and E coli HB101(pAML100), respectively.

Applicants disclose primers used to obtain pAML100 from *Bacillus* sp. KSM-AP1378. The strain has been deposited under FERM BP-3048 on August 8, 1990 (page 6). However it is not apparent whether the deposit is readily available to the public. An affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his/her signature, and registration number, stating that the specific strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 8 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 2 recites “functional fragment”. In addition to  $\alpha$ -amylase activity,  $\alpha$ -amylase may have other functions such as immunogenic activity, for example, and a functional fragment may be represented by different fragments of the same sequence with regard to different activities.

It is unclear what “inverted” means in the context of claim 3.

Claims 8 and 10 recite “the nucleic acid sequence of SEQ ID No. 2”, while SEQ ID NO:2 is an amino acid sequence. Claims 8 and 10 are indefinite because the specific hybridization conditions are not recited and therefore, it is unclear what is within the scope of the claims.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-8, 10 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsukamoto et al. or Yuuki et al.

Tsukamoto et al. and Yuuki et al. (form PTO-1449) teach a DNA encoding alkaline liquefying  $\alpha$ -amylase from *Bacillus* sp. #707 and *Bacillus licheniformis*,

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respectively. They disclose vectors containing said DNAs and cells transformed with the same. DNAs disclosed by Tsukamoto et al. and Yuuki et al. encode amino acid sequences which have about 87% and 69% of identical residues with SEQ ID NO:2, respectively. Therefore, they can be construed as DNAs encoding SEQ ID NO:2 having substitutions, deletions and additions (claim 3). They will hybridize with SEQ ID NO:1 under some hybridization conditions (claims 8 and 10).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukamoto et al. or Yuuki et al.

Tsukamoto et al. or Yuuki et al., *supra*, teach residues which constituted an active center of an *Bacillus*  $\alpha$ -amylase (p.29, lines 4-10; page 30, Fig.3 of Tsukamoto et al. and page 1153 of Yuuki et al.).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to find a fragment of alkaline liquefying  $\alpha$ -amylase from *Bacillus*

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sp. KSM-AP1378 retaining  $\alpha$ -amylase activity and a fragment of SEQ ID NO:1 encoding thereof. It is obvious that residues 100-330 of SEQ ID NO:2 are reasonably expected to retain function.

One skilled in the art would have been motivated to find a fragment retaining  $\alpha$ -amylase activity because smaller molecules are more convenient in many applications, such as production of antibodies or detergent compositions, for example.

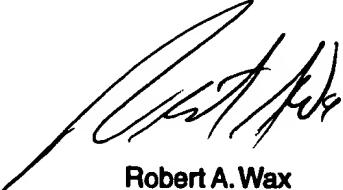
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

Elizabeth Slobodyansky, PhD

September 25, 1998



Robert A. Wax  
Supervisory Patent Examiner  
Technology Center 1600